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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,639	02/03/2004	Tommy R. Shedd	CEHR 03-13-02	8781

27370 7590 01/25/2005

OFFICE OF THE STAFF JUDGE ADVOCATE
U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
ATTN: MCMR-JA (MS. ELIZABETH ARWINE)
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EXAMINER

LARKIN, DANIEL SEAN

ART UNIT PAPER NUMBER

2856

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,639	SHEDD ET AL.	
	Examiner	Art Unit	
	Daniel S. Larkin	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 11-25 is/are rejected.
- 7) ☐ Claim(s) 6-10 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>23 June 2004</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Drawings

1. The drawings are objected to because of the following:

Reference box "32", as shown in Figure 1, should be labeled -- controller --.

Reference box "69", as shown in Figure 12, should be labeled -- amplifier --.

Reference box "140", as shown in Figure 12, should be labeled

-- terminal panel --.

Reference box "144", as shown in Figure 13, should be labeled

-- solenoid valve --.

Reference box "146", as shown in Figure 13, should be labeled -- sampler --.

Reference box "148", as shown in Figure 13, should be labeled

-- control sampler--.

Reference box "422", as shown in Figure 13, should be labeled

-- power supply --.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

Reference numeral "73", as disclosed on page 10, paragraph [0049], line 9, does not appear in the drawing figures.

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3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

Reference numeral "77" does not appear within Figure 4, as suggested by the disclosure on page 12, paragraph [0053], line 3.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "71" has been used to designate both a "drain-post chamber", as shown in Figure 4, and "legs", also shown in Figure 4.

5. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so

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as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

7. The disclosure is objected to because of the following informalities:

Page 3, paragraph [0010], line 2: A -- comma -- should be inserted prior to the term "such".

Page 3, paragraph [0011], line 2: A -- comma -- should be inserted prior to the term "such".

Page 3, paragraph [0014], line 2: A -- comma -- should be inserted prior to the term "such".

Page 4, paragraph [0019], line 9: The designation "-+" after the term "system" should be deleted.

Page 5, paragraph [0021], line 10: A -- comma -- should be inserted prior to the term "such".

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Page 6, paragraph [0026], line 1: The designation "3a" should be corrected to read -- 3A -- which is consistent with the drawing figure.

Page 6, paragraph [0027], line 1: The designation "3b" should be corrected to read -- 3B --.

Page 6, paragraph [0029], line 1: The designation "5a" should be corrected to read -- 5A --.

Page 6, paragraph [0030], line 1: The designation "5b" should be corrected to read -- 5B --.

Page 6, paragraph [0032], line 1: The designation "7a" should be corrected to read -- 7A --.

Page 6, paragraph [0033], line 1: The designation "7b-7c" should be corrected to read -- 7B-7C --.

Page 6, paragraph [0034], line 1: The designation "8a" should be corrected to read -- 8A --.

Page 6, paragraph [0035], line 1: The designation "8b" should be corrected to read -- 8B --.

Page 5, paragraph [0021], line 1: The designation "11a-11b" should be corrected to read -- 11A-11B --.

Page 8, paragraph [0042], lines 1 and 4: A -- comma -- should be inserted prior to the term "such".

Page 8, paragraph [0043], line 10: The numerals "1 and "4" should be corrected to read -- one -- and -- four --.

Page 8, paragraph [0043], line 11: The numerals "1" and "2" should be corrected to read -- one -- and -- two --.

Page 8, paragraph [0044], line 7: Reference numeral "20" should be corrected to read -- 22 --.

Page 9, paragraph [0047], line 1: The designation "3a-3b" should be corrected to read -- 3A- 3B -- which is consistent with the drawing figures.

Page 9, paragraph [0047], line 3: The term prefereablycylindrical" should be corrected to read -- preferably cylindrical --.

Page 10, paragraph [0048], line 1: The phrase -- as shown in Fig. 4, -- should be inserted after the numeral "64".

Page 11, paragraph [0051], line 1: The designation "5a-5b" should be corrected to read -- 5A-5B --.

Page 15, paragraph [0061], line 10: The designation "8a-8b" should be corrected to read -- 8A-8B --.

Page 16, paragraph [0061], line 3: The term "heart" should be corrected to read -- heat --.

Page 17, paragraph [0066], line 3: An end parenthesis --) -- should be inserted after the term "gorbuscha".

Page 19, paragraph [0072], line 12: The numeral "10" should be corrected to read -- ten --.

Page 28, paragraph [0098], line 5: Reference numeral "414" should be corrected to read -- 415 --. Appropriate correction is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-5 and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,058,763 (Shedd et al.) in view of US 5,804,705 (Florion et al.).

With respect to the limitations of claim 1, the reference to Shedd et al. ('763) discloses an apparatus and a method for automated biomonitoring of water quality whereby the reference discloses an exposure chambers (20); a water inlet (16) for directing water to the exposure chamber (20); an electrode (24, 25) for sensing and quantifying ventilatory behavior and body movement of an aquatic organism into data and outputting the data as a behavioral signal, col. 4, lines 13-14 and 32-39; and a controller (30) for receiving the behavioral signal and determining a plurality of ventilatory parameters based on the behavioral signal, col. 4, lines 42-47. The reference to Shedd ('763) fails to disclose a recirculating device for recirculating water to the exposure chamber. The reference to Florion et al. discloses a method and apparatus for monitoring aqueous media using aquatic animals, whereby the reference discloses the use of exposure chambers (3); a water inlet for directing water into the bottom of the exposure chamber (3); electrodes (2) to monitor the responses of the aquatic animals to their environment; a controller/computer (6) for receiving the behavioral results of the animals; and a recirculating apparatus/stirring tank (11) for

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recirculating water back to the exposure chambers, col. 5, lines 65-67 through col. 6, lines 1-15. Providing a recirculating apparatus would have been obvious to one of ordinary skill in the art as a means of replenishing the liquid within the exposure chambers while also providing control of the temperature of the water entering the chambers, so that measurements of the behavioral responses of the animals/organisms can be more easily correlated to changes in physical and chemical changes, such as pH and oxygen, or the presence of hydrocarbons or other toxic materials, rather than a change in temperature of the water.

With respect to the limitations of claim 2, the reference to Shedd et al. ('763) discloses that the sample stream used in the exposure chamber (20) is diverted through a water quality sensor (40). The reference to Shedd et al. fails to provide a water reservoir or a pump for pumping the water through the water quality sensor and to an exposure chamber. The reference to Florion et al. discloses that the recirculating apparatus comprises a water reservoir (11) and a pump (16) for pumping water from the reservoir (11) to the exposure chambers (3). The reference to Florion et al. additionally discloses that a device may be provided for automatically sampling specimens of liquids for analyses; and providing a unit for monitoring various physico-chemical parameters, such as pH, oxygen, turbidity, conductivity, ammonia, etc...) via specific physico-chemical sensors. Providing a water reservoir and a pump would have been obvious to one of ordinary skill in the art as a means of always having a ready supply of fluid and means to move the fluid whenever or wherever needed.

With respect to the limitation of claim 3, the reference to Shedd et al. ('763) fails to explicitly disclose a water distribution manifold for dividing the water before it enters the exposure chamber. The reference to Florion et al. discloses a water distribution manifold for use with two exposure chamber (3), as shown in Figure 4. Providing a manifold would have been obvious as a means of providing multiple connections to multiple exposure chambers without the need for extensive piping.

With respect to the limitations of claim 4, the reference to Shedd et al. ('763) discloses that the water characteristic data from the water quality sensor (40) may be used to corroborate the ventilatory parameter analysis by the controller (30), col. 4, lines 51-67 through col. 6, lines 1 and 2.

With respect to the limitation of claim 5, the reference to Shedd et al. ('763) discloses that the water characteristic includes dissolved oxygen level and temperature, col. 4, lines 52-54.

With respect to the limitation of claim 11, the reference to Shedd et al. ('763) discloses that the controller further determines when various parameters are out of limits.

With respect to the limitations of claim 12, the reference to Shedd et al. ('763) discloses that the controller determines ventilatory frequency, col. 2, line 21, average depth (36), and cough rate (34) of the organism based on the behavioral signal.

With respect to the limitation⁴ of claim 13, the reference to Shedd et al. ('763) discloses that a water sampler (54) responsive to the controller (30) is provided for

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sampling water supplied to the exposure chamber (20) for subsequent analysis, col. 5, lines 3-13.

With respect to the limitation of claim 14, the reference to Shedd et al. ('763) discloses that water discharged to the environment may be directed into a holding tank when the controller determines that one or more of the ventilatory parameters exceeds a threshold, col. 5, lines 14-42; col. 6, lines 15-38; and col. 11, lines 12-15.

With respect to the limitation of claim 15, the reference to Shedd et al. ('763) discloses that a plurality of compartments can be used to each house an organism, see Figure 4.

With respect to the limitation of claim 16, both Shedd et al. ('763) and Florion et al. disclose that the aquatic organism/animal is a fish.

10. Claims 17-19 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,804,705 (Florion et al.) in view of US 6,058,763 (Shedd et al.).

With respect to the limitations of claim 17, the reference to Florion et al. discloses a method and apparatus for monitoring aqueous media using aquatic animals, comprising the steps of: delivering water to be evaluated to a water reservoir (11); pumping (16) the water from the reservoir (11) to an exposure chambers (3) housing at least one aquatic organism/animal (1); measuring electrical signals generated by the at least one aquatic organism/animal (1), col. 1, lines 42-45; draining the water in the exposure chamber (3) back into the reservoir (11); and pumping (16) the water back into the exposure chamber (3). The reference to Florion et al. fails to disclose a plurality

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of ventilatory parameters of the aquatic organism/animal based on the electrical signals. The reference to Shedd et al. ('763) discloses an apparatus and a method for automated biomonitoring of water quality whereby electrical signals generated by an aquatic organism (22) can be used to determine a plurality of ventilatory parameters of the aquatic organism (22). Monitoring ventilatory parameters of aquatic organisms would have been obvious to one of ordinary skill in the art because ventilatory responses are known to be reliable indicators of toxins and pollutants in wastewater and drinking water systems; thus providing early indicators of impending damage to aquatic ecosystems and possible harm to humans.

With respect to the limitation of claim 18, the reference to Florion et al. discloses that a device may be provided for automatically sampling specimens of liquids for analyses; and providing a unit for monitoring various physico-chemical parameters, such as pH, oxygen, turbidity, conductivity, ammonia, etc...) via specific physico-chemical sensors.

With respect to the limitations of claim 19, the reference to Florion et al. discloses delivering the water to a water distribution manifold, as shown in Figures 2-4, wherein the water distribution manifold divides and distributes the water into a plurality of exposure chambers (3) each housing an aquatic organism/animal (1). Although the reference to Florion et al. fails to disclose a single exposure chamber divided into a plurality of compartments, the examiner argues that the reference to Florion et al. provides a functionally equivalent bio-system, whereby water quality is determined using a plurality of organism/animals and a plurality of containers/compartments.

Alternatively, the reference to Shedd et al. ('763) disclose an exposure chamber (20), as shown in Figure 4, divided into a plurality of compartments (66) each containing an aquatic organism (22). Dividing a single chamber into a plurality of compartment would have been obvious to one of ordinary skill in the art as a means to test multiple samples or organism without having to increase the size of the measuring system.

With respect to the limitation of claim 21, the reference to Florion et al. discloses maintaining the temperature of the water being evaluated within the exposure chamber (3) at a predetermined value, col. 5, lines 5-13 and col. 6, lines 4-9.

With respect to the limitations of claim 22, the reference to Florion et al. discloses a method and apparatus for monitoring aqueous media using aquatic animals, comprising the steps of: delivering water to be evaluated to a water reservoir (11); pumping (16) the water from the reservoir (11) to an exposure chambers (3) housing at least one aquatic organism/animal (1); maintaining the temperature of the water being evaluated within the exposure chamber (3) at a predetermined value, col. 5, lines 5-13 and col. 6, lines 4-9; measuring electrical signals generated by the at least one aquatic organism/animal (1), col. 1, lines 42-45; draining the water in the exposure chamber (3) back into the reservoir (11); and pumping (16) the water back into the exposure chamber (3). The reference to Florion et al. fails to disclose a plurality of ventilatory parameters of the aquatic organism/animal based on the electrical signals. The reference to Shedd et al. ('763) discloses an apparatus and a method for automated biomonitoring of water quality whereby electrical signals generated by an aquatic organism (22) can be used to determine a plurality of ventilatory parameters of the

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aquatic organism (22). Monitoring ventilatory parameters of aquatic organisms would have been obvious to one of ordinary skill in the art because ventilatory responses are known to be reliable indicators of toxins and pollutants in wastewater and drinking water systems; thus providing early indicators of impending damage to aquatic ecosystems and possible harm to humans.

With respect to the limitation of claim 23, the reference to Florion et al. discloses that a device may be provided for automatically sampling specimens of liquids for analyses; and providing a unit for monitoring various physico-chemical parameters, such as pH, oxygen, turbidity, conductivity, ammonia, etc...) via specific physico-chemical sensors.

With respect to the limitations of claim 24, the reference to Florion et al. discloses delivering the water to a water distribution manifold, as shown in Figures 2-4, wherein the water distribution manifold divides and distributes the water into a plurality of exposure chambers (3) each housing an aquatic organism/animal (1). Although the reference to Florion et al. fails to disclose a single exposure chamber divided into a plurality of compartments, the examiner argues that the reference to Florion et al. provides a functionally equivalent bio-system, whereby water quality is determined using a plurality of organism/animals and a plurality of containers/compartments. Alternatively, the reference to Shedd et al. ('763) discloses an exposure chamber (20), as shown in Figure 4, divided into a plurality of compartments (66) each containing an aquatic organism (22). Dividing a single chamber into a plurality of compartments would

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have been obvious to one of ordinary skill in the art as a means to test multiple samples or organism without having to increase the size of the measuring system.

11. Claims 20 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,804,705 (Florion et al.) in view of US 6,058,763 (Shedd et al.) as applied to claims 17-19 and 22-24 above, and further in view of US 3,827,283 (Lerner et al.).

With respect to the limitation of claims 20 and 25, the references to Florion et al. and Shedd et al. both fail to disclose means for monitoring the water pressure of water entering the manifold. The reference to Lerner et al. discloses a fluid leakage measuring apparatus that utilizes a manifold to distribute fluid to a plurality of locations. The manifold is provided with a rotameter (3) which indicates the amount of fluid flowing into the manifold. Given that one of ordinary skill in the art would know the flow rate of fluid into the manifold, and would have the inherent capability to measure the inner diameter of the manifold, the examiner argues that one of ordinary skill in the art would have the requisite ability to convert these values into a pressure reading. Monitoring the pressure applied to the manifold would have been obvious to one of ordinary skill in the art as a means of providing sufficient flow to the exposure chambers without creating a disturbance for the aquatic organism/animal present in the exposure chamber.

Allowable Subject Matter

12. Claims 6-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel S. Larkin whose telephone number is 571-272-2198. The examiner can normally be reached on 8:00 AM - 5:00 PM Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on 571-272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel Larkin
AU 2856
21 January 2005


DANIEL S. LARKIN
PRIMARY EXAMINER